Participant Information Sheet and Assent Form for participants under the age of 16

Title of Study: The effect of early cryoprecipitate transfusion versus standard care in women who develop severe postpartum haemorrhage: A pilot cluster randomised trial (ACROBAT: Administering CRyoprecipitate in Obstetric Bleeding At an earlier Time)

Chief Investigator: Dr Laura Green
Sponsor: Queen Mary University of London

Why am I being given this leaflet?

This hospital is taking part in a research study about severe bleeding in childbirth where we need to give blood transfusions. This research will help us understand how to improve the care of women who suffer such heavy bleeding in the future.
This leaflet explains the research and what will happen if you want to take part. It is entirely up to you if you want to take part. Once you understand the leaflet, ask any questions you want and let us know what you decide. It is ok to say 'no', it will have no impact on the rest of your hospital visit or treatment. If you say 'yes' you can still change your mind later, just let someone know. Because you are under 16, we will also ask your parent or legal guardian about their opinion about your taking part in this study.

Why have I been invited to take part?

Because you experienced heavy bleeding during or after childbirth which required emergency treatment with blood transfusion. This hospital is taking part in a research study called ACROBAT. This means in some hospitals, some of the different blood products are given in a slightly different order to try and stop the bleeding. In some other hospitals nothing changes at all.

At the time when you needed blood transfusion, we couldn't tell you or your parent/guardian, because it was an emergency and we needed to treat you as quickly as possible. We are telling you about this now and ask for your consent to be included in this study.

What will happen to me if I agree to be included in the study?

If you're happy to take part, we would only like to collect information that has already been collected about your health from your hospital records. You would not receive any further treatment or tests.

What is normally done when someone loses a lot of blood in childbirth?

What we call severe blood loss is rare, and most women don't need any blood transfusions. Sometimes (in 1 in 50 births), a blood transfusion is necessary.
When this happens, special rules are followed, and different blood products are given in a particular order. Normally, we first give **red blood cells** and **plasma** (the liquid part of the blood); if that does not help, we give two more products called **cryoprecipitate** and **platelets** – these are blood products that can help the blood to clot.

We don't know if that's the best order to give these blood products. We are interested in studying the order in which we administer **cryoprecipitate.** This is a very safe product that helps the blood to clot, and it's been used in the UK for more than 40 years already. We think that if we give cryoprecipitate earlier, at the same time as the first blood transfusion, this might help stop the bleeding more quickly – but we can't be sure yet, which is why need to perform this research study.

Green L, *et al. BMJ Open* 2020; 10:e036416. doi: 10.1136/bmjopen-2019-036416

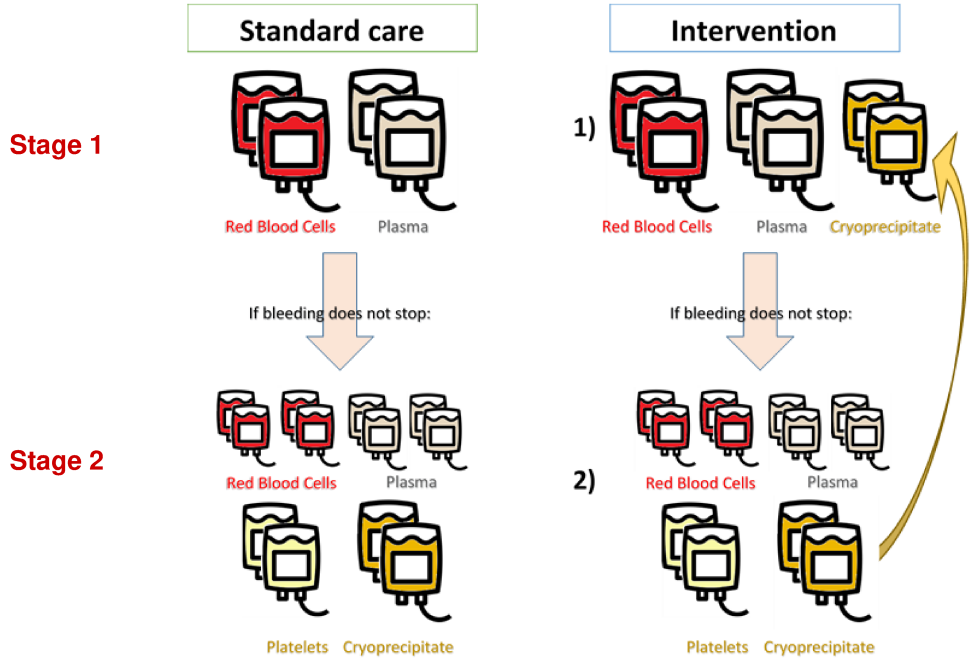
How does the ACROBAT study work?

In order to prove our theory, we would need to perform a very large trial. Before we run such a large trial, we need to do "test run" of the study, to find out whether we are going about it in the right way. This is called a pilot study. We want to find out if it is possible to give cryoprecipitate earlier and collect some more information about how best to run the big trial.

We plan to recruit 200 women across 4 hospitals in the UK. In the study, hospitals are randomly allocated into 2 groups: 1) standard care and 2) intervention.

- **Standard care group**: all women who have a baby in these hospitals will receive exactly the same treatment as usual. This means that cryoprecipitate is given later on, and in some cases may not be given at all.

- **Intervention group**: all women who have a baby in these hospitals and who have heavy bleeding that requires blood transfusion, will receive cryoprecipitate a little earlier. The rest of the treatment is exactly the same as normal.



If you would like to know which group your hospital is in, you can ask us.

How have I been identified?

A member of the research team has looked through the medical records and has seen that you had the kind of bleeding after childbirth that needed a transfusion of blood products.

What are the benefits for me?

We can't promise that you will do better by taking part in the study. But we hope that the information from the study will help us improve the care of mums who lose a lot of blood in the future.

What are the risks for me?

We do not expect there to be any risks for you, because cryoprecipitate is already given as part of standard treatment to women who bleed heavily after childbirth. It's not a product,and it has been used safely in the UK for over 40 years.

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What if there is a problem?
If you have any concerns about any aspect of this study, you or your parent can talk to the research team. If you don't want to do that, you can talk to the Patient Advice and Liaison Service (PALS) at your hospital. These people have nothing to do with this study. You can contact them under the phone number below.

Do I have to take part, and what happens if I change my mind?
It is up to you to decide whether to take part in the research or not. If you decide to be included in the study, you will be free to change your mind at any time, without giving a reason, and then we won't collect any further data for this study.

Will my taking part in the study be kept confidential?
Yes, we are only collecting data that does not identify you. You will not be mentioned in any publication. Only the hospital team and your GP will know about you taking part in this study.

Who is organising and funding the research, and what happens to my data?
The study is funded by Barts Charity. Queen Mary University of London organises this study and will analyse and publish the results. An independent group of people, called a Research Ethics Committee, has reviewed this study and said it is OK for us to run it.

Who should I contact for further information?
If you have any questions, you and your parent/guardian can talk to any of the people below:

Principal Investigator name/contact details:

Research midwife name/contact details:

Patient Advice and Liaison Service (PALS):

Assent Declaration **UIN:** ☐☐☐|☐☐☐

Local principal investigator name: _____

Participant name: _____

Please circle your answers:

Has somebody explained this project to you?	Yes / No
Do you understand what this project is about?	Yes / No
Have you asked all the questions you want?	Yes / No
Have you had your questions answered in a way you understand?	Yes / No
Are you happy to take part?	Yes / No

If you're answer is "Yes" to all of this, write your name to confirm: _____

The person who explained the study to you will sign and date below:

_____ Date: _____

Thank you for your time to read this leaflet!

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